

REMARKS

The Office Action of November 17, 2009 has been reviewed and the Examiner's comments have been carefully considered. Claims 1 and 5-9 are pending in the application, with claim 1 in independent form.

Rejection Under 35 U.S.C. § 103(a)

Claims 1 and 5-9 are rejected under 35 U.S.C. § 103(a) as being obvious over United States Patent No. 5,458,854 to Burns (hereinafter "Burns") in view of United States Patent No. 3,918,909 to Arlman (hereinafter "Arlman").

The Examiner asserts that Burns discloses a one piece collection container assembly having an elongate tubular housing (12) having opposed first and second ends (as shown in Fig. 2), a solid partition (38) contacting a sidewall (22) of the tube forming a closed bottom (38) and positioned within said housing between the first and second ends (as shown in Fig. 2). The Examiner further contends that the housing defines a volume for specimen collection and containment therein between the first end and said partition, the second end forming a false bottom having a bottom end below the partition having an annular skirt (37) having an opening (47) therein.

The Examiner acknowledges on paged 2-3 of the Office Action that Burns does not disclose that the bottom of the tube is semi-spherical, however, the Examiner asserts that such a modification is "an obvious design consideration" as a mere change in shape that does not patentably distinguish over the prior art. The Examiner further contends that Arlman discloses a specimen collection tube with a false bottom surface having a semi-spherical shape. The Examiner asserts that it would have been obvious to combine the assembly of Burns with the false bottom having a semi-spherical shape of Arlman to allow compatability with standard clinical equipment because such a shape was well known at the time the invention was made.

Applicant respectfully traverses this rejection.

Applicant's independent claim 1 recites, in relevant part, "said second end forming a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom

comprises an opening therein” (emphasis added). On page 2 of the Office Action, the Examiner acknowledges that Burns does not disclose a false bottom having a semi-spherical shape, however, the Examiner contends that absent a critical teaching and/or showing of unexpected results from the tube having a semi-spherical bottom, such a modification is an obvious design choice as “a mere change in shape that does not patentably distinguish... over the prior art”. The Examiner contends that one skilled in the art would be motivated to modify Burns to include a bottom having a semi-spherical shape to allow the tube to be compatible with common standard clinical equipment and instrumentation depending on the exact intended use of the tube.

Applicant submits that Burns specifically requires that the bottom end of the tube includes a cylindrical shape for receiving a portion of the cap thereon. As recited in Burns at column 5, lines 7-12, “As shown in Fig. 6, cap 14 is readily compatible with skirt 37 on the lower portion of the container. Space 68 of the cap receives the skirt of the container. *When the cap is positioned on the bottom of the container during fluid collection, the cap provides a means for allowing the container to be placed upright on a flat surface.*” Accordingly, the bottom of the tube of Burns is cylindrical to allow the cap to be engaged therewith to provide a means for allowing the container to be placed on a flat surface during fluid collection. Burns is entirely silent as to: 1) that the bottom end of the tube is semi-spherical; and 2) that the bottom of the tube is adapted for common instrument compatibility.

Applicant further submits that Arlman fails to disclose or suggest a false bottom having a semi-spherical shape, as recited in Applicant’s independent claim 1. As a preliminary matter, the Examiner contends that “Arlman teaches a specimen collection tube with a false bottom surface having a semi-spherical shape”, however, the Examiner provides no indication as to where this alleged false bottom surface having a semi-spherical shape is disclosed. Arlman discloses a tubular member 1 having a projection 2 including a separating agent 8 and provided with a closing cap 7. *See* Arlman, column 4, lines 40-53. A cover 11 is disposed on the opposite end of the tubular member 1, and in certain embodiments such as shown in Fig. 1, a reaction compartment 10 disposed within the tubular member 1 includes a tubular part 13 which is provided with a rim 14 at the upper end to which cover 11 is secured. The lower end of the tubular part 13 includes a bottom 12 having an aperture 15 having a membrane 16 disposed

thereover. *See* Arlman, column 4, lines 54-68. During use of the device of Arlman, the cap 7 is removed and the membrane 16 is pierced. Under the influence of gravity, the substance contained in the reaction compartment 10 moves into the separating agent 8 contained in the projection 2. *See* Arlman, column 5, lines 23-39.

Arlman fails to disclose or suggest: 1) a false bottom portion, as both projection 2 and reaction compartment 10 form portions of the functional mixing chamber of the device of Arlman; and 2) that the bottom of the tube is adapted for common instrument compatibility, as the washing liquid is discharged through projection 2, and thus, projection 2 cannot be adapted for engagement with common instrument compatibility for housing the tube.

In addition, MPEP § 2144.04(C) states:

“The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, *without the benefit of appellant’s specification*, to make the necessary changes in the reference device.” Citing *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984). (Emphasis added).

Applicant submits that neither Burns, nor Arlman, nor the combination of Burns and Arlman, disclose or suggest a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom comprises an opening therein, as recited by Applicant’s claim 1. Applicant further submits that neither Burns nor Arlman provide a motivation or reason for a worker in the art to modify Burns to include a semi-spherical bottom. In fact, Burns expressly teaches away from the inclusion of a semi-spherical bottom for the reasons discussed herein.

Applicant submits that impermissible hindsight was required for the Examiner to reach the conclusion that Burns could be modified as a mere change in shape to disclose the limitations of independent claim 1. Applicant further submits that impermissible hindsight was required for the Examiner to reach the conclusion that Burns could be modified by the teachings of Arlman to disclose the limitations of independent claim 1.

The Examiner cannot use the claims as a blueprint for locating separate claim elements in separate prior art references without considering the teachings of the prior art as a whole and without considering the complete teachings of the separate references. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999); *See also In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965) (“It is impermissible...to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”). In particular, “[i]t is impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). In addition, the Federal Circuit has stated that “a critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field,” *In re Kotzab* 217 F.3d. 1365, 1369, (Fed. Cir. 2000).

As admitted by the Examiner on page 2 of the Office Action, the “difference between Burns and the instant invention is the bottom of the tube being semi-spherical.” Applicant respectfully submits that the limitation requiring that the bottom of the tube be semi-spherical is not merely an obvious design consideration, but rather an inventive aspect of the present application to allow the bottom of the tube to be compatible with common instrumentation. Neither Burns nor Arlman provide any disclosure, suggestion, or motivation to provide a false bottom having a semi-spherical bottom end. This aspect of the invention was clearly an inventive contribution to the then-accepted wisdom in the field.

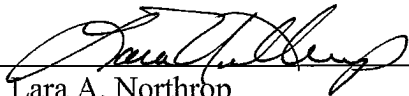
As discussed hereinabove, it has been held that it is impermissible to use the claimed invention as an instruction manual or template to piece together the teachings of the prior art so that the claimed invention is rendered obvious. Hindsight reconstruction cannot be used to pick and choose among isolated disclosures in the prior art to render obvious the claimed invention. Therefore, a *prima facie* case of obviousness has not been established.

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Dependent claims 5-9 depend directly or indirectly from independent claim 1 and are believed patentable for the reasons stated herein. Reconsideration and withdrawal of the rejection of claims 1 and 5-9 and allowance of all pending claims are respectfully requested.

Respectfully submitted,

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